

PSJ14 Janssen Opp Exh 36 – JAN00008227

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NUCYNTA®

2011 Business Plan

July 27, 2010

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Key Business Questions: NUCYNTA®

- What aspects of health policy require increased brand focus and organizational engagement?
- What level of influence can advocacy play in pain management?



Skeptical and habitual marketplace

- Are we focused on the most important channels? How are they prioritized?
- What are the outstanding barriers to improved market access and how do we address them?
- Is tier III status enough to achieve our commercial access goals?



Significant and increasing market access barriers

- How do we rapidly accelerate brand awareness across all customer segments?
- What is the optimal promotion mix and message platform to increase trial and sustained adoption by key customers?
- How do we evaluate our approach to the market given the growing influence of non-traditional stakeholders?



Low brand awareness & adoption across key customer segments

- What do we need to justify our premium over generic analgesic products?
- What evidence and investment is required to break the Vicodin/Percoet "habit"?
- How do we effectively promote the 'total story', e.g., better tolerance means more patients stay on NUCYNTA and realize the pain relief they need, benefit of lack of euphoria?



NUCYNTA not viewed as superior to oxy molecule



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2

Key Business Questions: Tapentadol ER

- What is the unmet need in the moderate-severe chronic pain market?
- What is the opportunity to influence HCP-patient dialogue regarding pain treatment?
- What aspects of health policy require increased brand focus and organizational engagement?

Skeptical and habitual marketplace

- Are we focused on the most important channels? How are they prioritized?
- What are the outstanding barriers to improved market access and how do we address them?
- How do we achieve comparable market access to the market leader?

Significant and increasing market access barriers

- Which patients can benefit from tapentadol ER? Who treats them, and where are they treated?
- How do we generate brand rapid awareness in a branded chronic pain market?
- How do we effectively support a broad launch at the local retail pharmacy?
- What is the optimal promotion mix and message platform to gain trial and adoption within the chronic pain market?
- Is TRF an opportunity to differentiate the brand vs. oxy or merely a cost of entry?

Low brand awareness & adoption across key customer segments

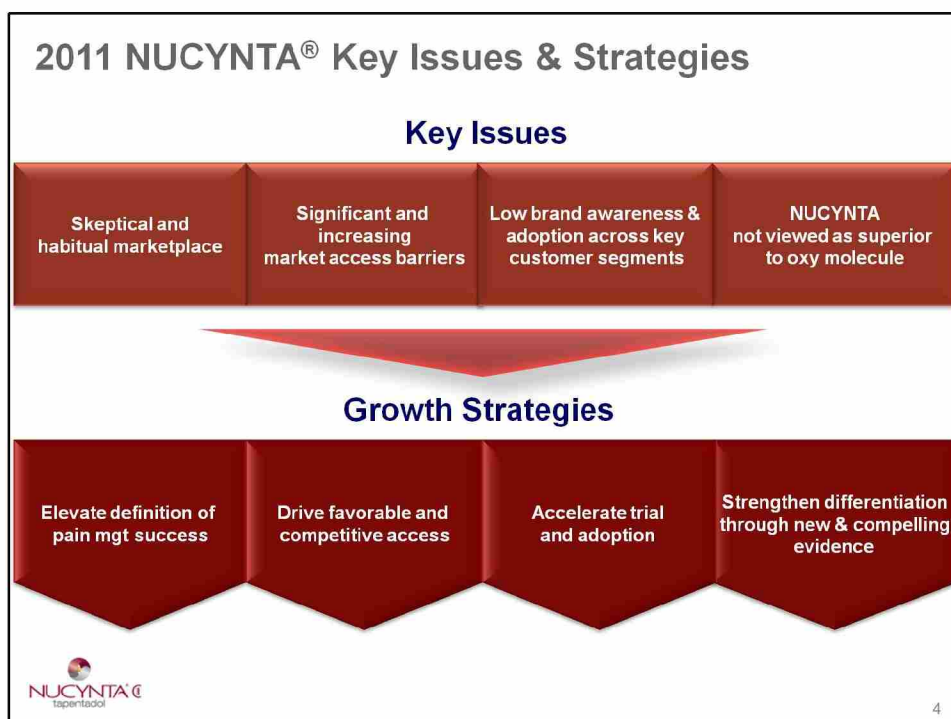
- Can tapentadol ER demonstrate lower abuse potential?
- What compelling evidence is required to engage HCPs earlier in treatment flow and ensure favorable/competitive market access?

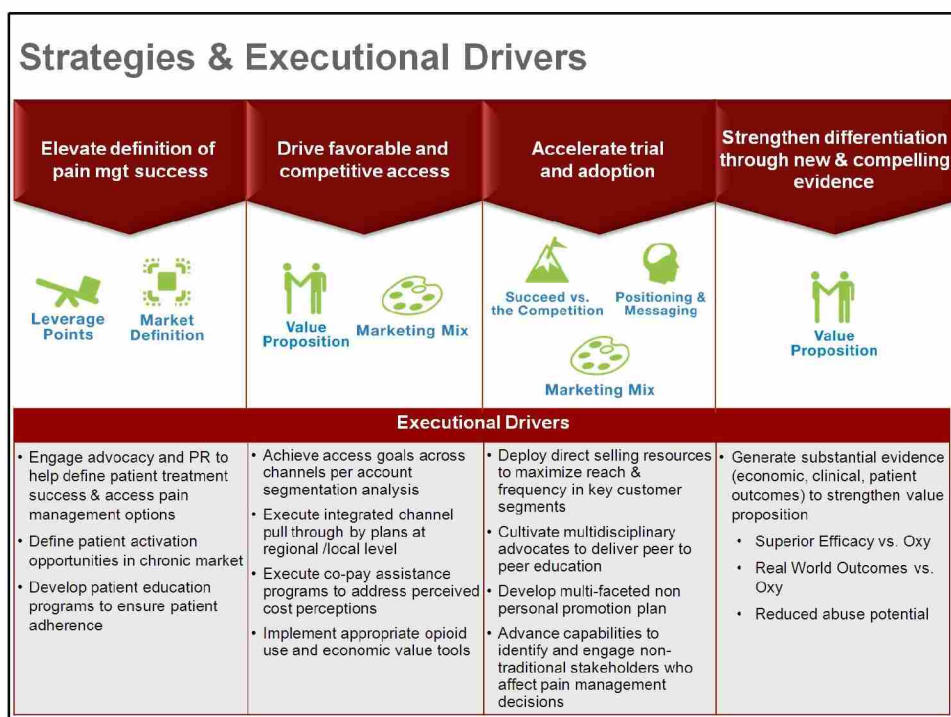
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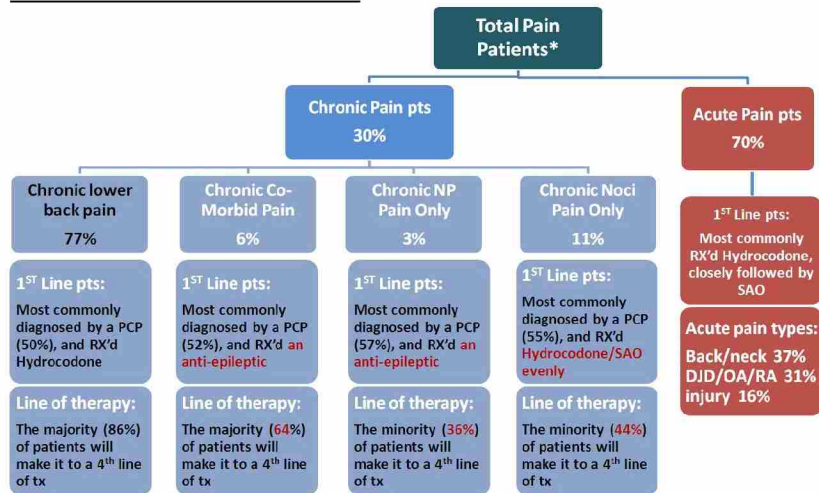
NUCYNTA® success requires integrated effort across stakeholders within their sites of care



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6

Pain Patient Flow Overview



81% of chronic pain patients will see a PCP at some point in their treatment, 29% see an Orthoped, and 18% see a Pain specialist

Institution influence: 39% of SAO acute Rx's are filled within 14 days of an institution visit, 30% for Vicodin acute Rx's, and 16% of LAO (chronic) Rx's

Implications:

- 1) Specialty productivity & PCP penetration
- 2) Institutional presence

*includes C3, C2 SAO, C2 LAO, Tramadol, AED, AD

7

Direct Selling Assumptions 2011

| | PAIN | AI/GI | CVI | COBI | SCG |
|------------------------|--|---|---|--|---|
| Target Audience | ~ 26 K <small>Pain Spec, Hi vol PCPs, Rheum, Neuro, ORS, mid levels (non retail excluding CVI accounts)</small> | ~ 24 K <small>PCPs Midlevels</small> | 2,600 hospital accounts <small>(127 hospital systems)</small> 75,000 contacts <small>(ORS, EM, PCP, mid-levels)</small> | ~ 3.5 K ONCs <small>GO, HEM, HO, ON, SQ, OMO, RO, ASO and all Mid-Levels assoc w/ Onc</small> | Key regional & national accounts |
| # reps | 459 | 474 | 334 | 162 | |
| Portfolio | NUC ELM | LEV, ACI REMI, NUC | DORI, NUC LEV IV, BIOPATCH | PROCRIT, DOXIL NUC | |

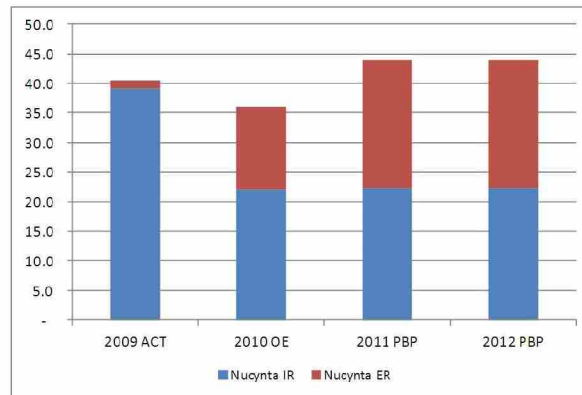


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8

2010 OE-PBP BME's – Total NUCYNTA®

| | 2009 ACT | 2010 OE | 2011 PBP | 2012 PBP |
|--------------|-------------|-------------|-------------|-------------|
| Nucynta IR | 39.2 | 22.2 | 22.2 | 22.2 |
| Nucynta ER | 1.5 | 13.8 | 21.8 | 21.8 |
| Total | 40.6 | 36.0 | 44.0 | 44.0 |



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9

| NUCYNTA® Key BME Investments – Total \$44MM (IR/ER) | | |
|--|--|-------------------------------|
| <u>Strategic Objectives</u> | <u>Tactics</u> | <u>\$'s in '000</u> |
| Elevate definition of pain mgt success | <ul style="list-style-type: none"> • Patient Education • Advocacy • Public Relations | \$6.6MM 15% |
| Drive favorable and competitive access | <ul style="list-style-type: none"> • Co-pay Assistance • Payer Programs | \$8.8MM 20% |
| Accelerate trial and adoption | <ul style="list-style-type: none"> • Sales Force Support • Promotional Medical Education • Non personal • Print & Electronic Media • Conventions and Exhibits • Training & Development | \$28.6MM 65% |
| Strengthen differentiation through new & compelling evidence | <ul style="list-style-type: none"> • Medical Affairs • Publications | Medical Budget |



10

SD Clutter

Current clutter between ED & PE

Lilly - 36 hr therapeutic window.

Pfizer will actively add to clutter – use us for both; Faster acting longer lasting

Habitual prescribing of PDE5s and SSRIs

Become second line therapy

As the pie grows a greater utility of non-indicated medication

SSRI/PRN use / cost

Life Style

Risk/benefit may not warrant Rx

Referrals to specialists (not a PCP responsibility)

Reimbursement issue

Patient/Physician Population Apathy

Target Seg. don't go to Dr.

Cheap, private, online options

Private condition; private soln

Persistence challenges

First to Market: Define the market with highest standards and optimize first mover position

n=12,000

Broaden awareness as "mainstream" prevalent and treatable condition

First to Market lets us prime market according to our standards

Set PRO outcome measures (partner)

Equal opportunity category

Huge buzz factor if harnessed correctly

Establish excellence in PE patient management

Treatment expectations

Capitalize on patient motivation to self assess appropriately / privately

Improve physician dialogue and diagnosis tools to differentiate from ED and allow DPX become treatment foundation

Product Attributes ("one minute wonder"; SSRI halo; black box)

Clinical Data Gaps (Concomitant use with PDE5 and SSRIs; Depressed patients; LT safety)

Internal comfort level with Brand / category message

Opportunity cost assoc w/product position

COGS + pricing model?

Lack of perceived medical legitimacy

Disease state understanding; "in your head"

Lack of a comorbid link

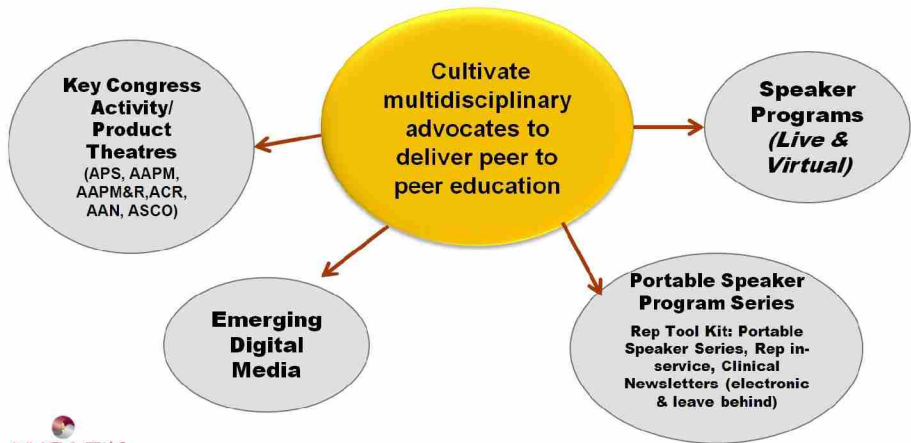
Managed Care coverage

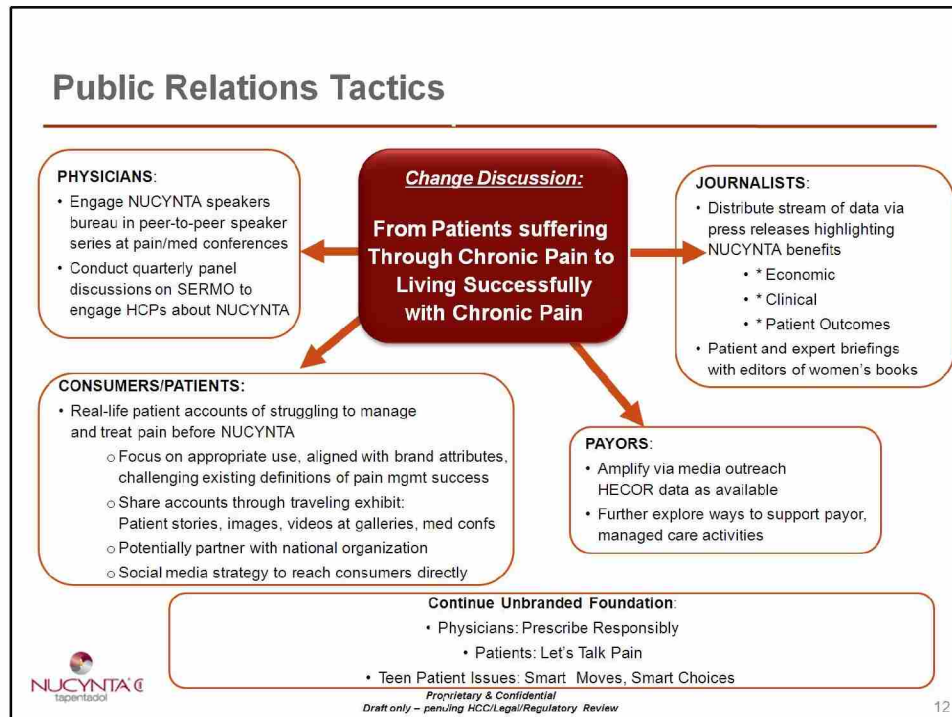
Net, through internal and external analysis we have identified 4 key areas for focus in 2004

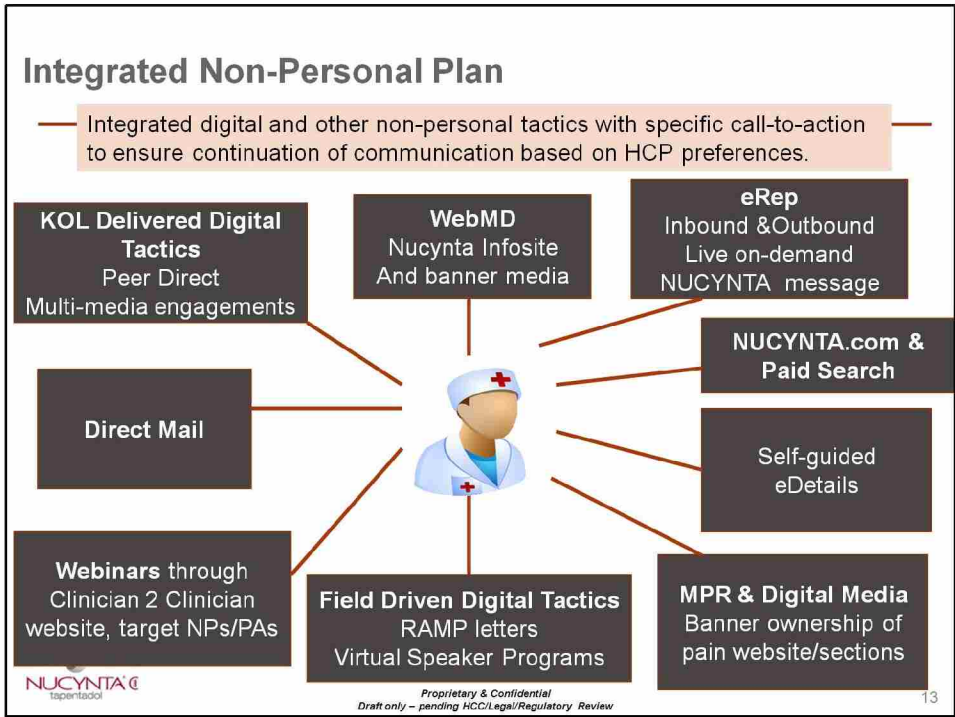
Sales for optimization : captures all of the changes to the organization and opportunity to leverage and grow

Promotional Medical Education Tactics

Accelerate trial and adoption







NUCYNTA Media Campaign

- Amplified campaign across various stakeholders for both NUCYNTA and tapentadol ER.
- Objective: To increase awareness and broaden reach among prescribers and payors
- Target Audiences:
 - PCP, Pain Specialists, PM&R, ORS, Oncologists, Rheum, Neurologists, Pharmacy and Payors



The banner features a lion on the left, the NUCYNTA tapentadol logo in the center, and a 'LEARN MORE' button. To the right, there is a section for 'IMPORTANT SAFETY INFORMATION' with a warning icon.

For the relief of moderate to severe acute pain in patients 18 years of age or older

NUCYNTA[®] tapentadol

OPIOID EFFICACY MEETS UNEXPECTED TOLERABILITY

▶ LEARN MORE

▶ FULL US PRESCRIBING INFORMATION

IMPORTANT SAFETY INFORMATION

• Like other drugs with mu-opioid agonist activity, NUCYNTA[®] is contraindicated in patients with significant respiratory depression, acute or severe bronchial asthma or hypercapnia in unmonitored settings or in the absence of resuscitative equipment. NUCYNTA[®] is contraindicated in patients who have or are suspected to have



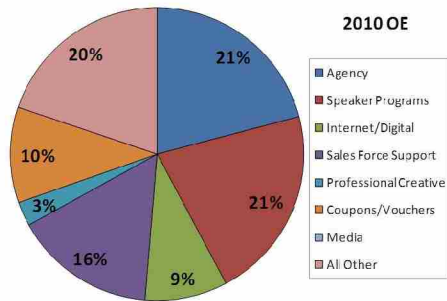
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14

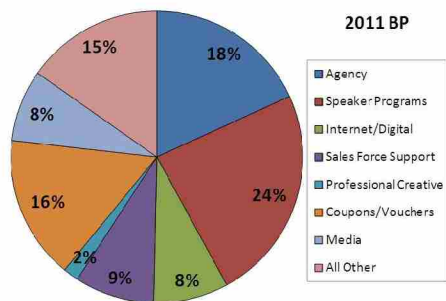
2010 OE-PBP BME's – TOTAL NUCYNTA

Drivers of Change Between 2010 and 2011

- Media
- Coupons
- Peer to Peer
- Public Relations



Total budget - \$36MM



Total budget - \$44MM



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15

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2011 MR Plan NUCYNTA IR/ER Details

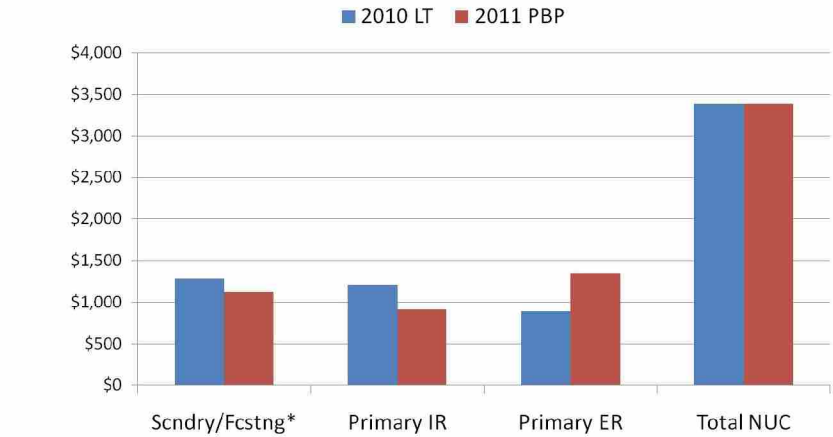
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16

2010 LT vs 2011 Nucynta Molecule Budget



*2010 includes LAO market analysis, retail and institutional patient flow expense
-does not include funding for REMS program support

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| NUCYNTA® Key Market Research Spend (\$2.3MM IR/ER) | | | |
|--|---|--------------------------------------|--------------------------------------|
| Strategic Objectives | MR Spend | IR Spend | ER Spend |
| Elevate definition of pain mgt success | <ul style="list-style-type: none"> Consumer/Patient focused New stakeholder research | \$145k \$100k | \$75k \$50k |
| Drive favorable and competitive access | <ul style="list-style-type: none"> Managed care – prescriber Competitive response / other | \$50k | \$50k \$100k |
| Accelerate trial and adoption | <ul style="list-style-type: none"> Message alignment, User study Message refinement, creative refresh Awareness/tracking SFE tracking | \$150k \$140k \$275k \$200k | \$265k \$190k \$275k \$200k |
| Strengthen differentiation through new & compelling evidence | | | |



18

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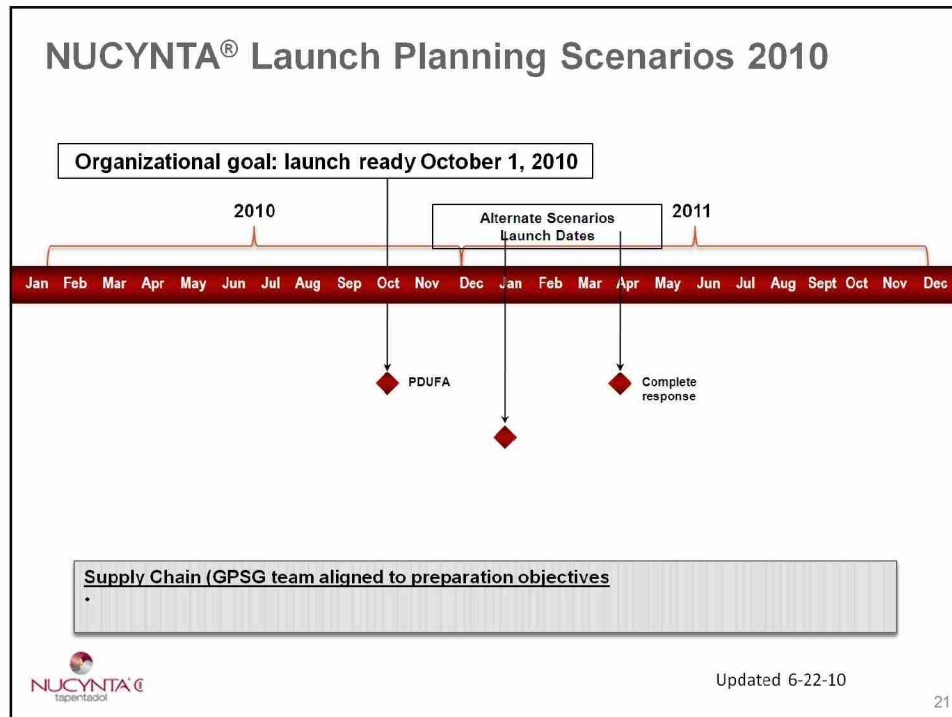
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Key Prescriber Insights: NUCYNTA®

| | Drivers | Barriers | Key Learnings |
|------------------|---|---|---|
| Primary Care | <ul style="list-style-type: none"> - Comparable efficacy to gold standard, Oxy IR - GI tolerability - Low perceived addiction and/or abuse potential | <ul style="list-style-type: none"> - Low awareness - Cost/access issues - No meaningful translation of MOA - Low recognition/concern re: GI side effects w/ SAOs | <p>Low awareness inhibiting trial and use where comfort & familiarity are key drivers. No recognition of need for dual pathway treatment in acute pain. Need to drive awareness and trial in LBP patient</p> |
| Pain Specialists | <ul style="list-style-type: none"> - Recognize huge unmet need in pain management; greater willingness to trial - Pain management experts; understand and appreciate dual MOA | <ul style="list-style-type: none"> - Cost/access not as big an issue; prior auths can be rate-limiting - Using Nucynta in more difficult to treat chronic pain - Efficacy questionable in refractory pain patients | <p>Most conclude dual pathway MOA provides a more comprehensive pain approach as well as opioid-sparing effects. Need to assure use in appropriate patient types.</p> |
| Orthopedists | <ul style="list-style-type: none"> - Effective post-op pain relief - GI tolerability | <ul style="list-style-type: none"> - Relevance of MOA - Cost/access not big issues for post-op pain patients, unless hospital will not stock | <p>MOA not important; focus should be on GI tolerability allowing dose to efficacy in post-op patients.</p> |



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2/26/10 King announced resubmission of Remoxy to FDA in 4Q10 (delayed from mid 2010). New launch estimate 2-3Q11.

2011 Strengths

- NME including ER TRF at launch
- Dual MOA, MU/NRI, provide opioid sparing effects
- Significantly better GI tolerability and low rates of pruritus
- Low discontinuation and higher global patient satisfaction rates
- Robust clinical data- efficacy across multiple pain models, including neuropathic pain
 - Proven efficacy vs gold standard comparator
 - Long term safety data
- Large SOV w/personal selling
- Diverse company w/large resources
- Low drug/drug interactions
- Core Pain Specialist KOL's



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2011 Weaknesses

- Serotonin syndrome and SSRI labeling
- Maximum dose limits ability to convert from competitors
- Relative contribution of norepinephrine vs. mu-opioid benefit has not been quantified and relation to efficacy in NP is tangential
- Alcohol contraindication
- Higher rates of headaches (CNS)
- Underdevelopment of current (Pain) KOL base in certain specialties (PCP, ONC, RHEUM)
- Sales force inexperience in severe, chronic pain



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2011 Opportunities

- Assess abuse and diversion from launch
- Opioid of choice in patients w/neuropathic symptoms
- Generate data for better patient outcomes and MRU
- Prospectively prove superiority (efficacy and tolerability)
- Advocacy, Employers and Quality Organizations have growing influence
- REMs could increase comfort of HCPs to Rx LAO CII's
- Contract for preferred placement in MCOs
- Channel specific approach for managed care
- Oxycontin fatigue w/payers/Purdue irresponsibility
- Opportunity in elderly (dissatisfied w/current tx) especially in OA
- Large portion of chronic pain is mixed
- Engage patients
- Terms & conditions of oxy contract are up for negotiation
- Non face-to-face selling



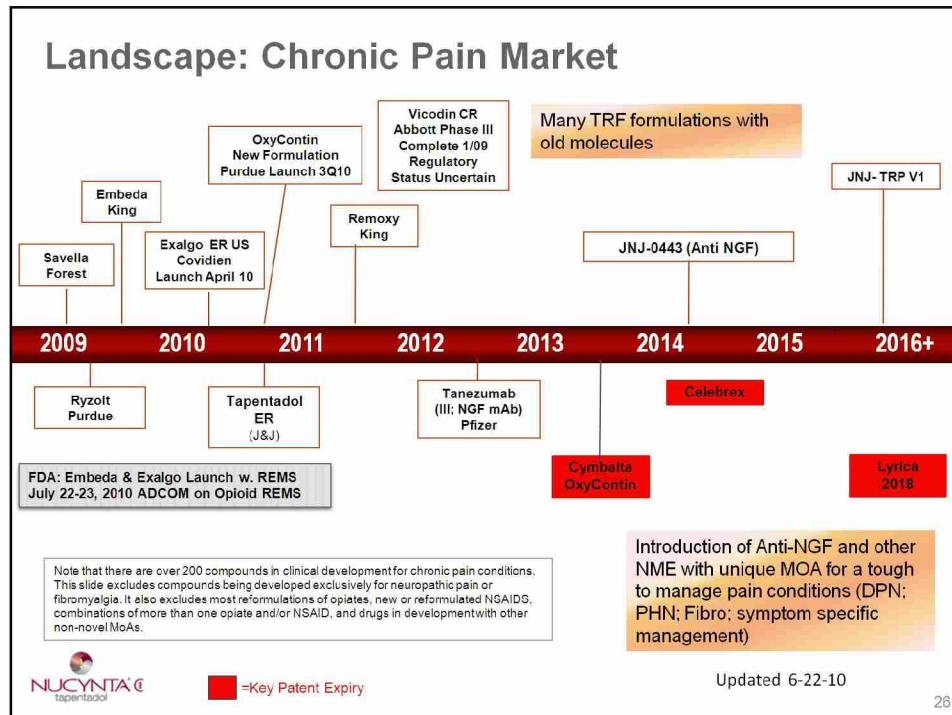
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2011 Threats

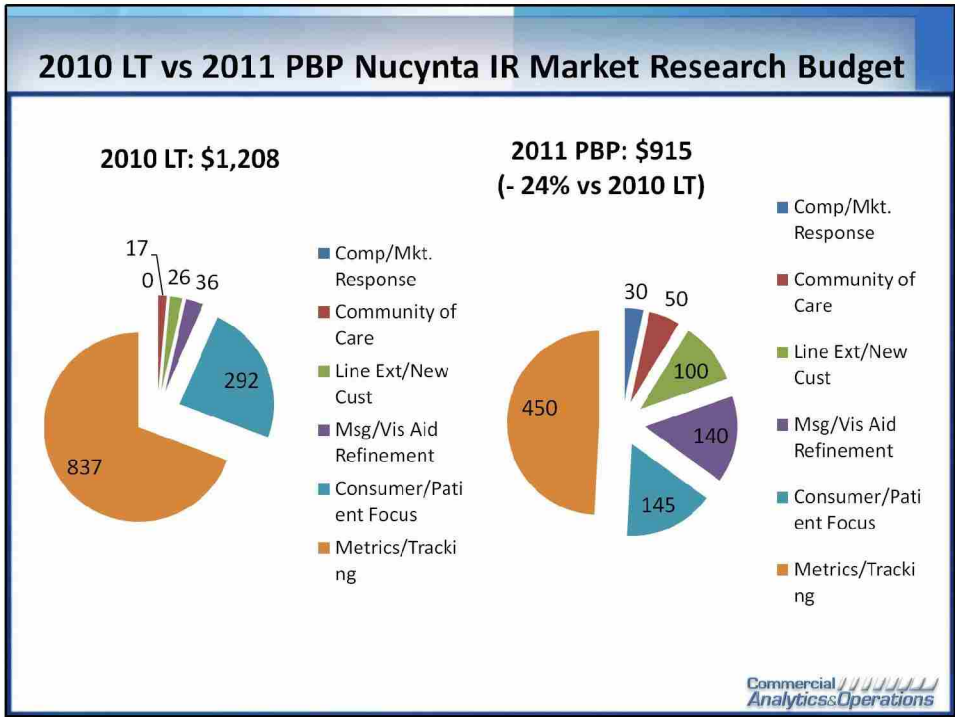
- Low brand awareness
- Confusion between tramadol and tapentadol
- Level of education in large segment of audience do not appreciate benefit
- Access block by competitors in key plans
- Oxycontin TRF, promoting something new
- Possible new managed care tiering structure
- Reduced SOV due to noise in market around TRF and REMs methodology
- Purdue pre-positioning NUCYNTA ER trial negatively
- Very low penetration across all specialties
- Pharmacy stocking

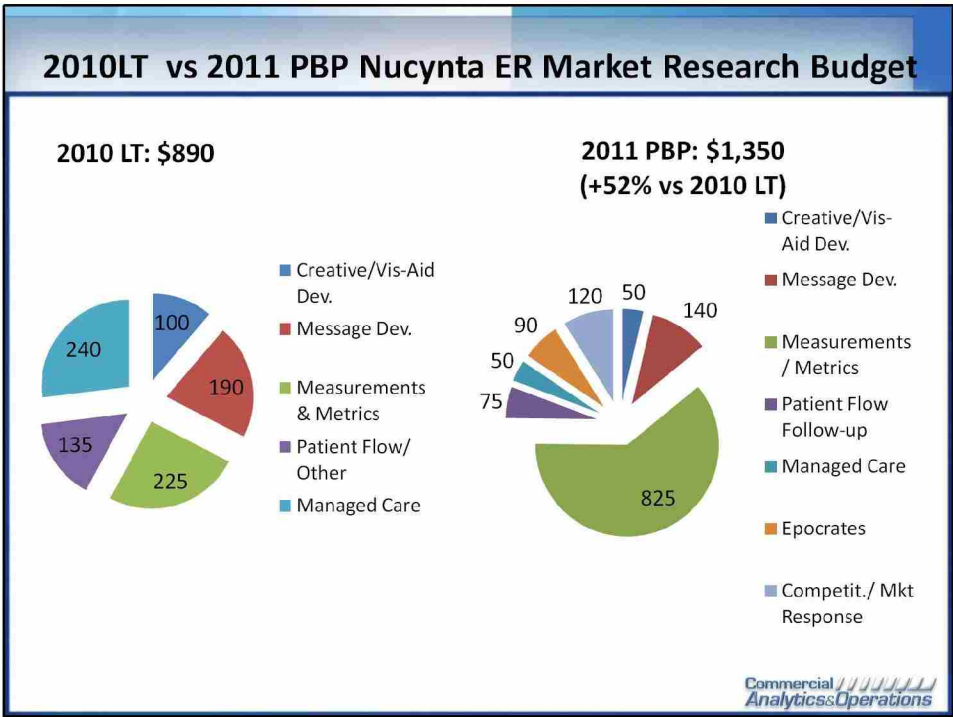


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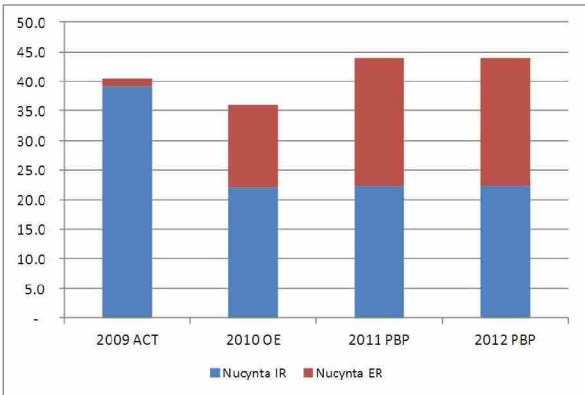
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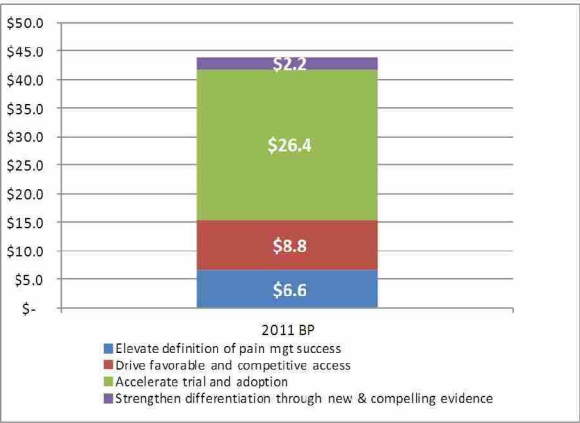
2010 OE-PBP BME's – TOTAL NUCYNTA

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|--------------|-------------|-------------|-------------|-------------|
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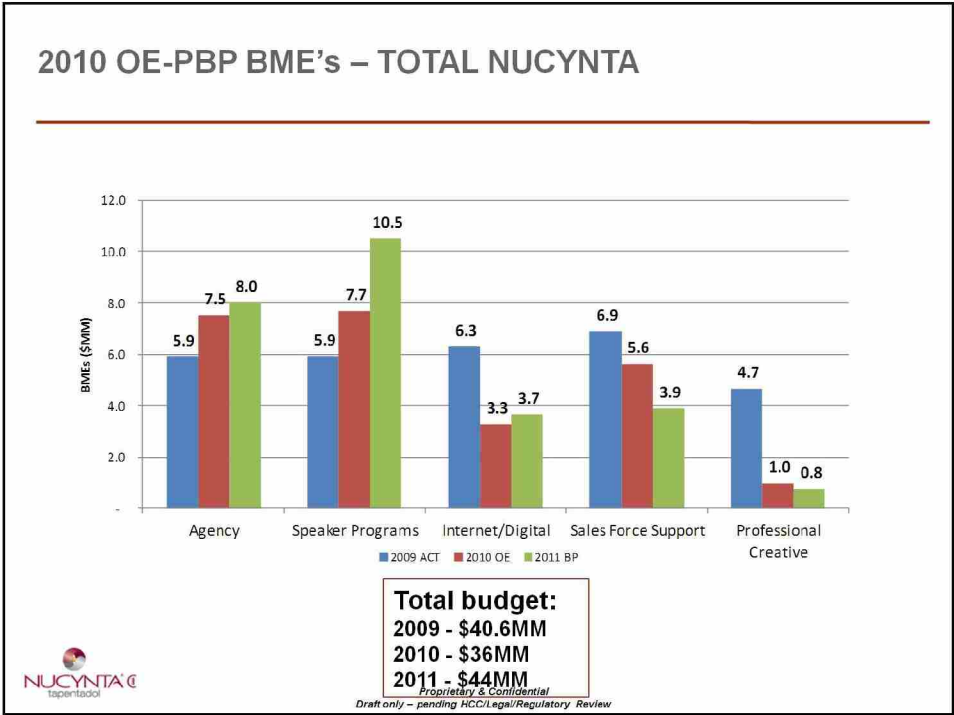
2011 Spend by Strategy – TOTAL NUCYNTA



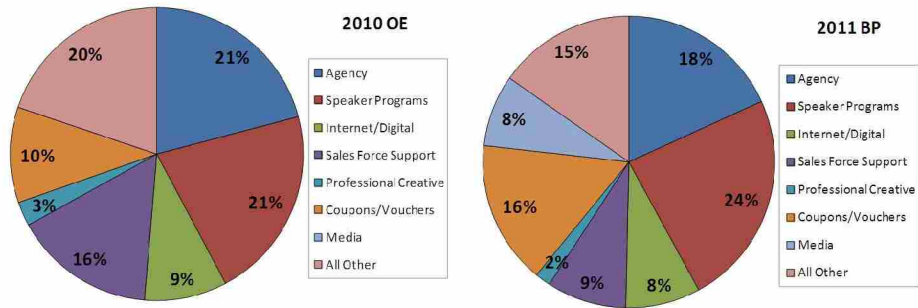
Total budget - \$44MM

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30



2010 OE-PBP BME's – TOTAL NUCYNTA



Total budget - \$36MM

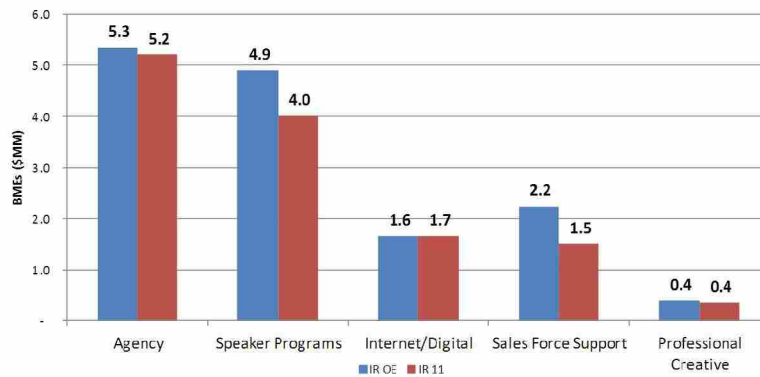
Total budget - \$44MM



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32

2010 OE-PBP BME's – NUCYNTA IR



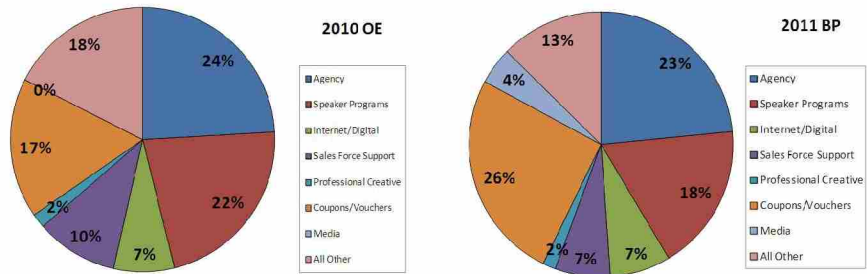
Total budget:
 2009 - \$39.2MM
 2010 - \$22.2MM
 2011 - \$22.2MM



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33

2010 OE-PBP BME's – NUCYNTA IR



Total budget - \$22MM

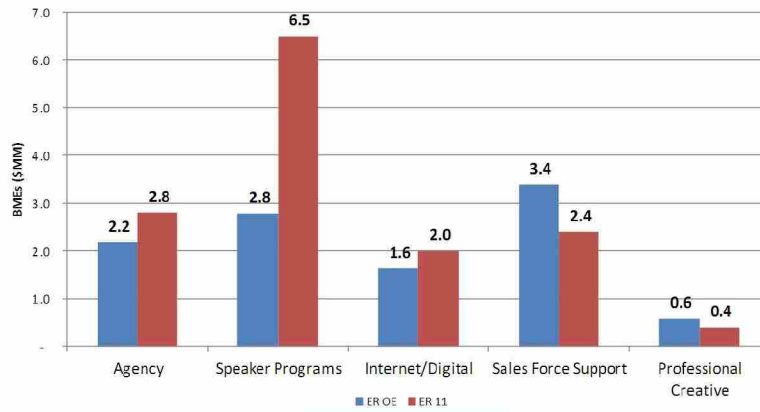
Total budget - \$22MM



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34

2010 OE-PBP BME's – NUCYNTA ER



Total budget:

2009 - \$1.5MM

2010 - \$13.8MM

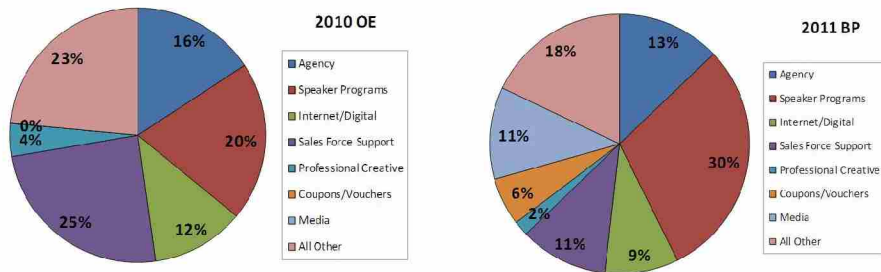
2011 - \$23.8MM



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35

2010 OE-PBP BME's – NUCYNTA ER



Total budget - \$14MM

Total budget - \$22MM



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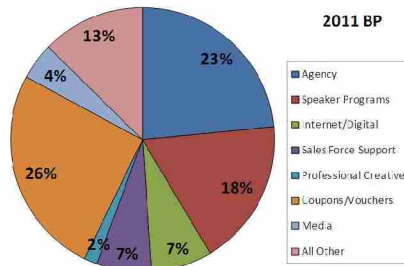
36

Backup

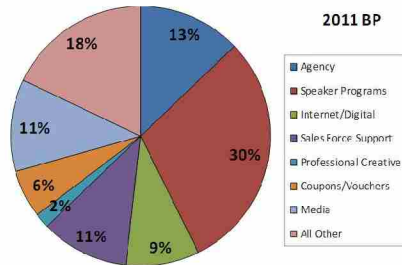


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2010 OE-PBP BME's – NUCYNTA IR



NUCYNTA - \$22MM

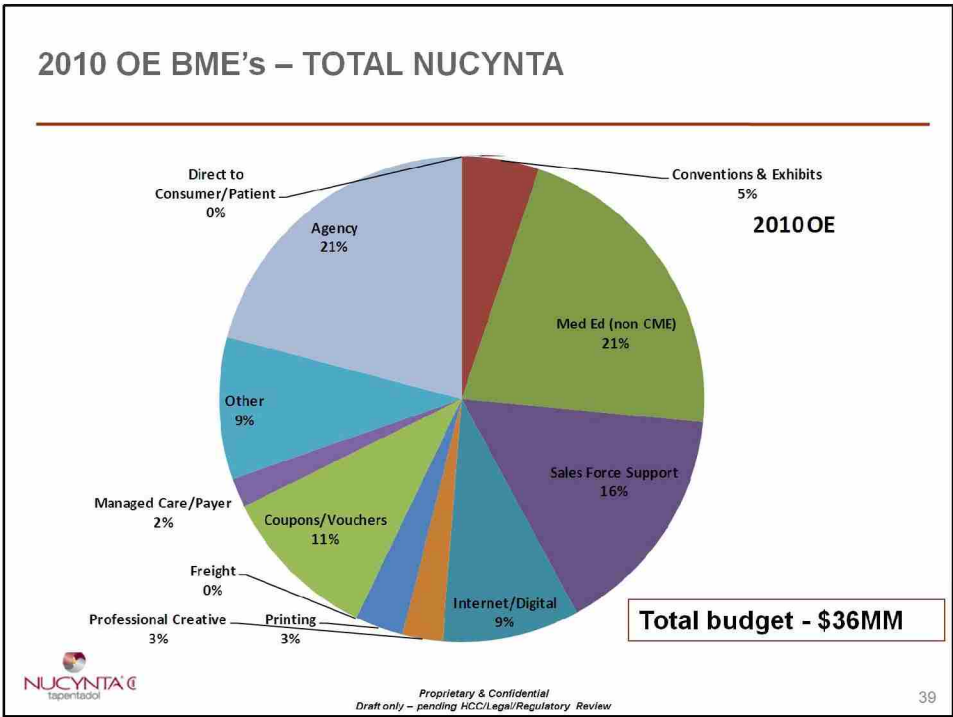


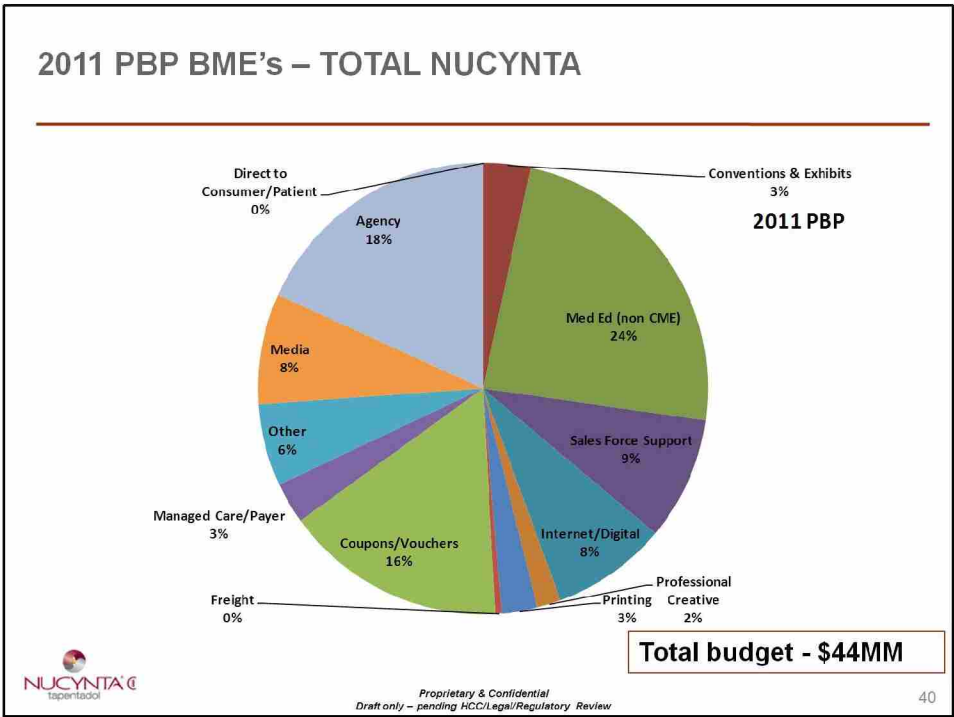
NUCYNTA ER- \$22MM



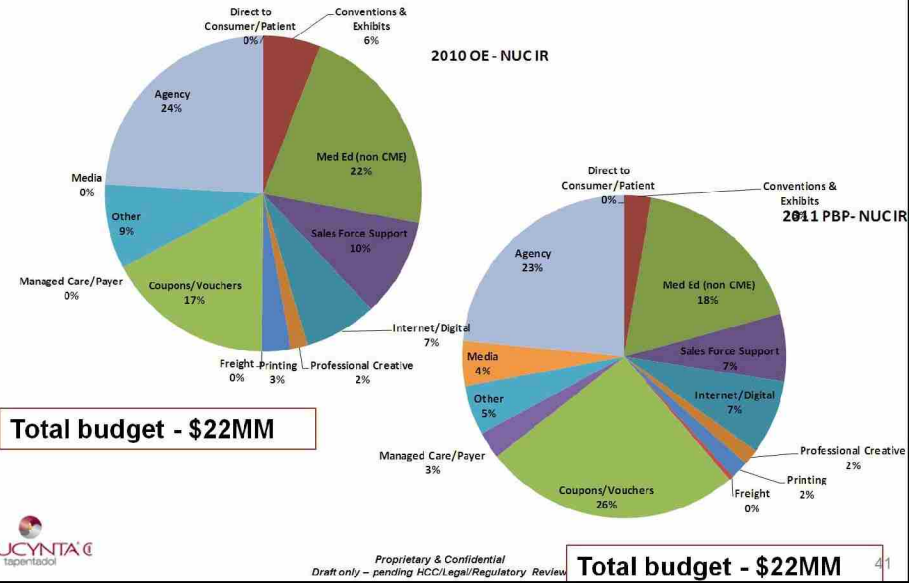
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38

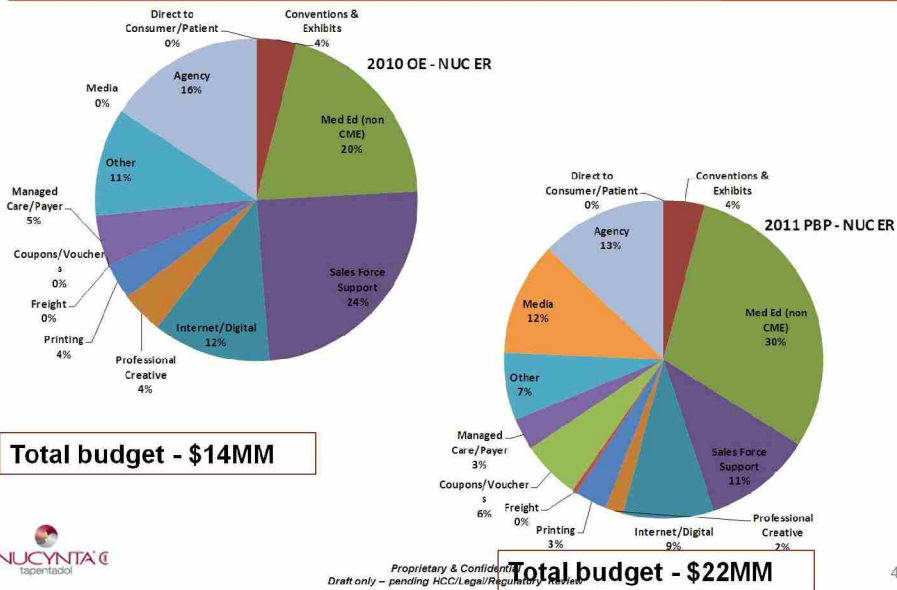




2010 OE-PBP BME's –NUCYNTA IR



2010 OE-PBP BME's –NUCYNTA ER



42

2010 OE-PBP BME's – TOTAL NUCYNTA

| | FY October Est | | OE | | FY | | |
|--|----------------|--------|--------|--|--------|--------|---------|
| | IR | ER | Total | | IR | ER | 2011 BP |
| Direct to Consumer/Patient | - | - | - | | - | - | - |
| Conventions & Exhibits | 1,310 | 550 | 1,860 | | 600 | 900 | 1,500 |
| Samples | - | - | - | | - | - | - |
| Med Ed (non CME) | 4,895 | 2,787 | 7,682 | | 4,000 | 6,500 | 10,500 |
| Ad Boards | - | - | - | | - | - | - |
| Speaker Programs | 4,895 | 2,787 | 7,682 | | 4,000 | 6,500 | 10,500 |
| Premiums | - | - | - | | - | - | - |
| Other professional | - | - | - | | - | - | - |
| Sales Force Support | 2,233 | 3,392 | 5,624 | | 1,500 | 2,392 | 3,892 |
| Sales Force Support | 2,233 | 3,392 | 5,624 | | 1,500 | 2,392 | 3,892 |
| Reprints/Promotional Literature/Sales Aids | - | - | - | | - | - | - |
| Internet/Digital | 1,648 | 1,633 | 3,281 | | 1,650 | 2,000 | 3,650 |
| Internet- Professional | 1,648 | 1,633 | 3,281 | | 1,000 | 1,600 | 2,600 |
| Internet- Consumer | - | - | - | | 650 | 400 | 1,050 |
| Professional Creative | 385 | 580 | 965 | | 350 | 404 | 754 |
| Physician Advertising | 385 | 580 | 965 | | 350 | 404 | 754 |
| Non-Personal | - | - | - | | - | - | - |
| Printing | 659 | 501 | 1,159 | | 400 | 711 | 1,111 |
| Freight | - | - | - | | 100 | 100 | 200 |
| Coupons/Vouchers | 3,800 | - | 3,800 | | 5,700 | 1,300 | 7,000 |
| Managed Care/Payer | 8 | 699 | 707 | | 600 | 700 | 1,300 |
| Other | 1,912 | 1,494 | 3,406 | | 1,100 | 1,494 | 2,594 |
| Public Relations | 500 | 400 | 900 | | 500 | 400 | 900 |
| All Other | 1,412 | 1,094 | 2,506 | | 600 | 1,094 | 1,694 |
| Media | - | - | - | | 1,000 | 2,500 | 3,500 |
| Agency | 5,339 | 2,177 | 7,516 | | 5,200 | 2,800 | 8,000 |
| Management Fees | 512 | 180 | 692 | | 200 | 300 | 500 |
| Creative Fees | 4,827 | 1,997 | 6,824 | | 5,000 | 2,500 | 7,500 |
| Total | 22,188 | 13,811 | 36,000 | | 22,200 | 21,801 | 44,001 |



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43

2010 OE-PBP Scenarios – NUCYNTA ER

ER Spend Scenarios

| | 2010 OE | | 2011 PBP | | 2010 OE | | 2011 PBP | |
|-------------------|---------|------|----------|------|----------|--|----------|--|
| | \$'s | | \$'s | | % Change | | % Change | |
| Launch - Oct '10 | \$ | 13.8 | \$ | 21.8 | | | | |
| Launch - Jan '11 | \$ | 11.0 | \$ | 21.8 | -20% | | 0% | |
| Launch - Apr '11 | \$ | 11.0 | \$ | 19.6 | -20% | | -10% | |
| Launch - July '11 | \$ | 11.0 | \$ | 18.5 | -20% | | -15% | |

**2010 - All Scenarios

\$4.5M shift of execution costs

**2011:

Jan Launch - Remains Flat

Apr Launch - Shift of 10% to 2012

July Launch - Shift of 15% to 2012



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44

Vision

NUCYNTA® redefines pain management success



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45

Positioning

For patients with moderate to severe pain, NUCYNTA® is the only broad coverage analgesic that provides superior outcomes.

Because:

1. Dual MOA, (MU/NRI) provide opioid-sparing benefits
2. Unsurpassed efficacy, established in the most prevalent pain conditions
3. Superior tolerability, leading to fewer discontinuations



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46

Market Fundamentals

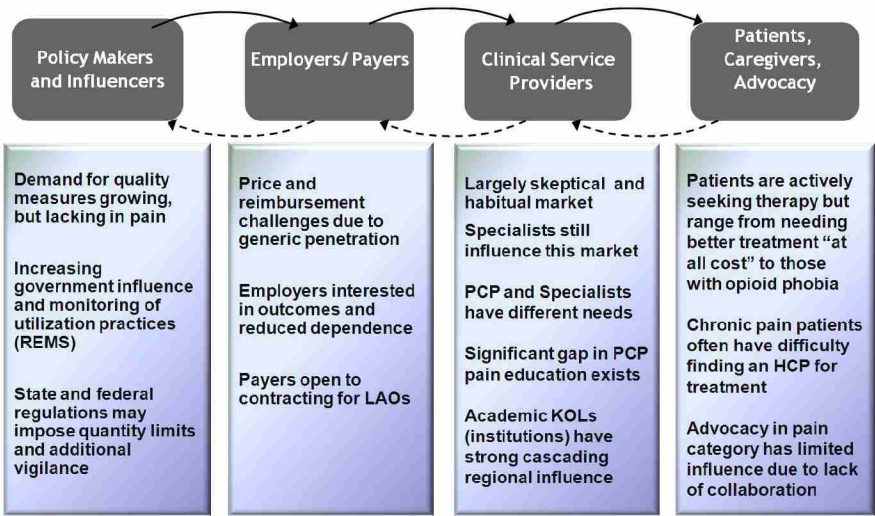
- **Pain Market Dynamics:**
 - CII market had variable growth in 2009 with the short acting market up 8.3%, and the long acting market down 1.5% vs. Prior year; Recent trends indicate return to growth in LAO market
 - SAO \$1.1 B (NSP \$ volume) market, with 49.7MM TRx (97% generic)
 - LAO \$5.5 B market, with 21MM TRx (62% generic)
 - Habitual and complacent prescribing patterns and high level of skepticism of new introductions
- **Changing Market Dynamics:**
 - Percocet (Oxycodone + APAP) accounts for 73% of SAO market volume, and it continues to maintain share in a growing market
 - Volume decline in the LAO market is driven by a number of factors including economic impacts, greater awareness of LAO abuse potential and potential impact of a class wide REMS program
 - Trend toward LAO- TRF formulations (75% of NDA filings TRF) may dictate future "cost of entry"
- **Treatment Dynamics:**
 - PCPs, Pain Specialists and Orthopedic Surgeons account for over 50% TRx volume and 75% DOT for both SAO and LAO markets
 - Back/Neck Patients dominate both acute and chronic pain types (37%, 77%)
- **Payor landscape:** Commercial (60%); Part D (21%) Medicaid (11%) Cash (8%)



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47

Key Stakeholders Have Varying Needs



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Unique Policies Surrounding CII's Affect Many Stakeholders

- Prescribers
 - Triplicates and e-prescribing oversight complicate prescription forms
 - Fear of DEA investigations and mandatory reporting of addicts
 - LAO-specific REMS training and education
- Patients
 - Regulations and media create opioid stigma and non-compliance
 - Quantity limits lead to frequent HCP and Pharmacy visits
- Federal/State Government
 - State Prescription Drug Monitoring Programs are costly to implement
 - DEA approved certification and monitoring for CII e-prescribing
 - FDA oversight of LAO REMS requirements
- Pharmacies
 - 222 forms complicate ordering process
 - Storage regulations (lockers) limit inventory options

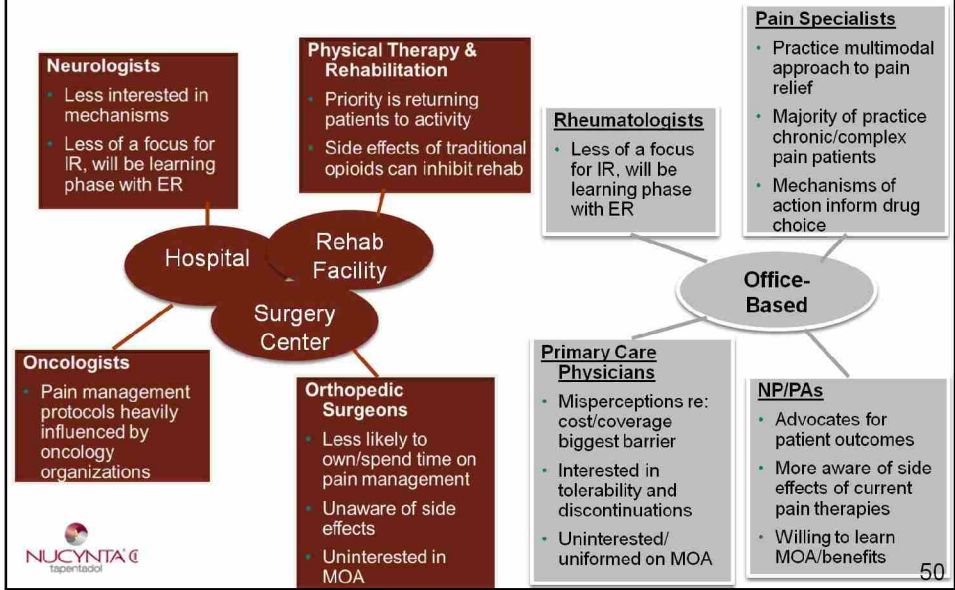


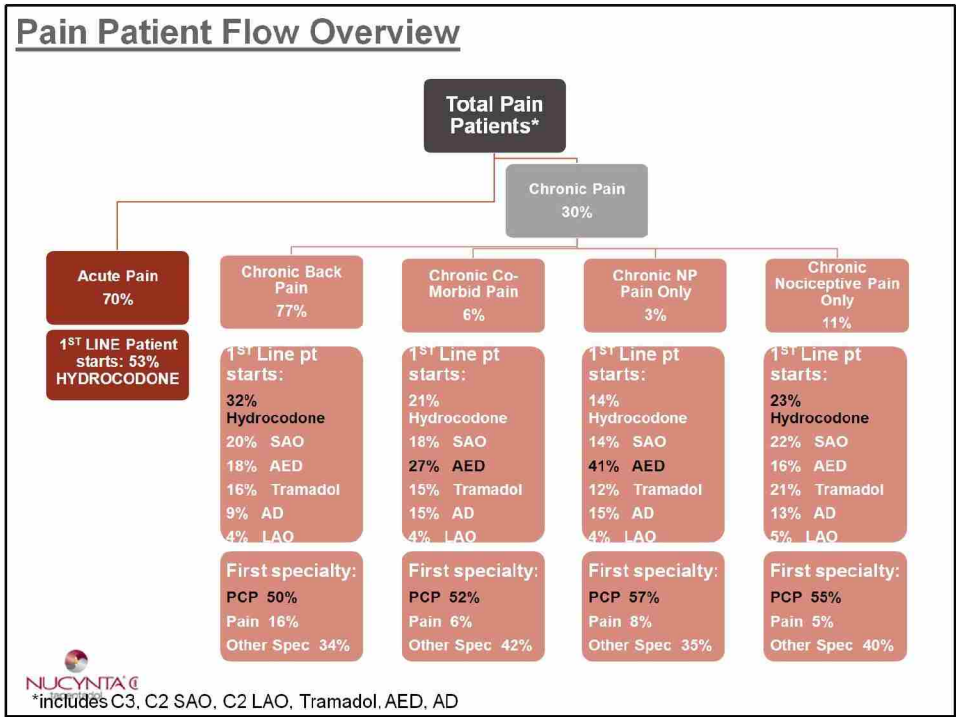
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49

E-prescribing—systems must be backed up daily, requires DEA approved certification and ongoing monitoring

Stakeholders and Sites of Care





SAO Market Overview

Market size: 53.2mm
TRx (2010 OE est), 7%
growth vs py

Est 79%
acute, 21%
chronic
TRx

Est 80%
20-64 yo,
20% 65+ yo

Average
persistence
of 1.9
months

**% NSP \$ by
channel:**

Retail 88%
LTC 3%
Hospital 3%
Clinics 2%
Federal 1%
Mail order 1%

**% TRx by
payor type:**

C3P 48%
Cash 12%
Medicaid 9%
Medicare 17%
Work Comp
2%
Other 13%

**% by DDD
(units) class of
trade:**

Hospital 34%
VA/DoD 30%
LTC 21%
Clinics 7%
Retail 3%
Misc 4%

% by dispensed

TRx:
Retail 92%
LTC 8%
Mail order <1%



LAO Market Overview

Market size: 21.6mm
TRx (2010 OE est), .7%
growth vs py

Est <5%
acute,
>95%
chronic
TRx

Est 70%
20-64 yo,
30% 65+ yo

Average
persistence
of 3.9
months

**% NSP \$ by
channel:**
Retail 87%
LTC 6%
Hospital 2%
Clinics 2%
Federal 1%
Mail order 2%

**% TRx by
payor type:**
C3P 47%
Cash 6%
Medicaid 7%
Medicare 26%
Work Comp
4%
Other 11%

**% by DDD
(units) class of
trade:**
Hospital 23%
VA/DoD 35%
LTC 26%
Clinics 5%
Retail 5%
Misc 5%

**% by dispensed
TRx:**
Retail 83%
LTC 16%
Mail order 1%



